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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,441	01/11/2002	Bernard A. Gonzalez	57287US002	8431
32692	7590	05/18/2005	EXAMINER	
3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427			CHIN, BRAD Y	
			ART UNIT	PAPER NUMBER
			1744	
DATE MAILED: 05/18/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/044,441

Applicant(s)

GONZALEZ ET AL.

Examiner

Brad Y. Chin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☒ Claim(s) 1-5 is/are allowed.  
6) ☒ Claim(s) 6 is/are rejected.  
7) ☒ Claim(s) 7-8 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

DETAILED ACTION

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et. al. [U.S. Patent No. 6,318,151].

Wang et. al. teach a method of determining the efficacy of the sterilization process, comprising the steps of: providing a sterilization sensor comprising an indicator that undergoes

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a change when exposed to an efficacious sterilization process (See col. 6, lines 8-13 – when the sensing element 125 is exposed to sterilant hydrogen peroxide vapor, the metal oxide surface absorbs the vapor molecules and causes oxidation. In this manner, it has been found that electrical resistance is reduced and, thus, the output signal generated by sensor 124 increases proportionally with increasing vapor concentration level); placing the sterilization sensor within a reader (See Figure 2 – sterilization sensor 124 placed within sterilant monitoring assembly 120), the reader adapted for inclusion within packs of goods to be sterilized and having chemical resistance capable of withstanding sterilizing conditions multiple times and through multiple uses (See Figure 5; See col. 2, lines 45-51 – sterilant monitoring assembly configured as self-contained, portable unit so as to be freely positionable proximate the sterilization apparatus to monitor levels of sterilant threat); placing the reader with the sterilization sensor inside a package of goods (See Figure 5; see col. 9, lines 1-5 – particularly preferred aspect of present monitoring system where monitoring assembly 120 is positioned in operative association with a carrier element 160 configured similar to an article, e.g. a container, to be sterilized by the apparatus 10); subjecting the package to sterilizing conditions (See Figure 5; see col. 9, lines 1-5 – particularly preferred aspect of present monitoring system where monitoring assembly 120 is positioned in operative association with a carrier element 160 configured similar to an article, e.g. a container, to be sterilized by the apparatus 10); and interrogating the reader without opening the package to learn whether the change has taken place (See col. 7, lines 59-64 – a data collection circuit 130 is operatively coupled to the sterilant sensor 124 to receive output signals from the sterilant sensor 124 as collected data. Transmitter 136 transmits signals representative of the collected data via a wireless connection, such as by radio frequency or near infrared, to a receiving element 147 of the remote communication unit 140 during a selected interval of operation). Wang et. al. fail to particularly teach that the sterilization sensor

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undergoes an optical change. It would have been obvious to one of ordinary skill in the art at the time the invention was made that the sensing element 125 undergoes an optical change because upon exposing the sensing element 125 to hydrogen peroxide vapor, the reaction caused by the metal dioxide surface absorbing the vapor molecules and causing oxidation would produce an optical, e.g. color, change.

***Allowable Subject Matter***

1. Claims 1-5 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: Applicant's claims 1-5, include the limitations for an apparatus and a method for determining the efficacy of a sterilization process and communicating the determination to a remote location, wherein a reader is adapted for inclusion within the pack of goods to be sterilized. The reader is adapted to receive the sterilization sensor, which undergoes an optical change; an illumination source for illuminating the sterilization sensor; a first color sensor for evaluating the illuminated sterilization sensor; an interpretation circuit; and a communication circuit. Kirckof et. al. teach machine readable sterilization indicators for monitoring articles to be sterilized, which includes a reader comprising an illumination source, a detector or first color sensor, an interpretation circuit, and a communication circuit. Kirckof et. al. describes the reader as a moving beam scanner, a handheld scanner, fixed mount scanners, and laser and solid state imagers – all external devices, independent of the sterilization indicators. Kirckof et. al. fails to teach that the sterilization sensor is received in the reader, and further fails to teach that the reader is adapted for inclusion within packs of goods to be sterilized. Joslyn teaches a sterilization analyzer, comprising a sterilization indicator, a reader, an interpretation circuit, and a communication circuit, that upon subjecting a package to sterilizing conditions interrogates the reader without

opening the package to learn whether particular sterilizing conditions have been met. Joslyn fails to teach that the sterilization indicator undergoes an optical change when exposed to an efficacious sterilization process, nor teaches placing the reader with the sterilization sensor and the supplemental components inside the package of goods. Wang et. al. teach a system and method for monitoring concentrations of sterilant within a sterilization apparatus, comprising a sterilization reader adapted to receive a sterilization sensor, an interpretation circuit, and a communication circuit. The reader is further adapted for inclusion within packs of goods to be sterilized. Wang et. al. fails to provide an illumination source and a first color sensor. None of the references teach the claimed limitations nor would it have been obvious to combine references to achieve the claimed inventive subject matter. Although Wang et. al. teaches a reader adapted for inclusion within packs of goods, it would not have been obvious, without destroying Kirckof et. al. or Wang et. al., to combine the references to teach the claimed limitations of Applicant's invention for providing a reader adapted to receive the sterilization indicator with an illumination source, first color sensor, interpretation circuit, and a communication circuit, all included within the packs of goods to be sterilized.

2. Claims 7-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: Claims 7 and 8 include the limitations for the method, wherein the reader, which comprises an illumination source, color sensor, interpretation circuit, and communication circuit, is adapted for inclusion within the pack of goods to be sterilized. Kirckof et. al. teach machine readable sterilization indicators for monitoring articles to be sterilized, which includes a reader comprising

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an illumination source, a detector or first color sensor, an interpretation circuit, and a communication circuit. Kirckof et. al. describes the reader as a moving beam scanner, a handheld scanner, fixed mount scanners, and laser and solid state imagers – all external devices, independent of the sterilization indicators. Kirckof et. al. fails to teach that the sterilization sensor is received in the reader, and further fails to teach that the reader is adapted for inclusion within packs of goods to be sterilized. Joslyn teaches a sterilization analyzer, comprising a sterilization indicator, a reader, an interpretation circuit, and a communication circuit, that upon subjecting a package to sterilizing conditions interrogates the reader without opening the package to learn whether particular sterilizing conditions have been met. Joslyn fails to teach that the sterilization indicator undergoes an optical change when exposed to an efficacious sterilization process, nor teaches placing the reader with the sterilization sensor and the supplemental components inside the package of goods. Wang et. al. teach a system and method for monitoring concentrations of sterilant within a sterilization apparatus, comprising a sterilization reader adapted to receive a sterilization sensor, an interpretation circuit, and a communication circuit. The reader is further adapted for inclusion within packs of goods to be sterilized. Wang et. al. fails to provide an illumination source and a first color sensor. None of the references teach the claimed limitations nor would it have been obvious to combine references to achieve the claimed inventive subject matter. Although Wang et. al. teaches a reader adapted for inclusion within packs of goods, it would not have been obvious, without destroying Kirckof et. al. or Wang et. al., to combine the references to teach the claimed limitations of Applicant's invention for providing a reader adapted to receive the sterilization indicator with an illumination source, first color sensor, interpretation circuit, and a communication circuit, all included within the packs of goods to be sterilized.

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**Conclusion**

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Y. Chin whose telephone number is 571-272-2071. The examiner can normally be reached on Monday – Friday, 8:00 A.M. – 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sun (John) Kim, can be reached at 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

byc  
May 12, 2005

  
JOHN KIM  
SUPERVISORY PATENT EXAMINER